K. 510(k) Summary

JUN 29 2006

Submitted by:

Cindy Rumple
Cook Urological, Incorporated and
Cook Ob/Gyn
1100 West Morgan Street
Spencer, Indiana 47460
March 31, 2006

Device:

Trade Name: Cook® Sonohysterography Biopsy Device

Proposed Classification Name: Endometrial Aspirator, Unclassified

Product Code: HHF, LKF

Regulation Number: 884.1060, Unclassified

Class: Class II

Predicate Devices:

The Cook® Sonohysterography Biopsy Catheter is comparable to existing predicate devices in distribution including the Tampa Catheter distributed by CooperSurgical, theEZ-HSG Catheter distributed by OBG Products, the Cook Hysterocath™ distributed by Cook Incorporated and Cook Ob/Gyn, the Goldstein Sonohysterography Catheter distributed by Cook Ob/Gyn. The biopsy function of the Cook® Sonohysterography Biopsy Catheter is similar to the Probet distributed by Gynetic Medical Products N.V., the Uterine Explora Model I distributed by Milex Products, the Wallace Suresample Endometrial Sampler distributed by Smiths Medical, the Pipelle de Cornier® Endometrial Suction Curette distributed by CooperSurgical, and the Aspiracath™ distributed by Cook Ob/Gyn.

Device Description:

The Cook® Sonohysterography Biopsy Catheter is used to access the uterine cavity for sonohysterography and to obtain endometrial biopsy, if indicated, utilizing the same device. The device is a single catheter designed to perform saline infusion sonohysterography then, if indicated, biopsy of the endometrium using the same device. The device will be supplied sterile and is intended for one time use. The materials used in the construction of the Cook® Sonohysterography Biopsy Device are well known in the medical field. Biocompatibility, Ethylene Oxide Residual, and Functional testing have shown that the materials and the device meet the test requirements and are safe and effective. Literary articles prove the usefulness of this type of device to the clinician and patient population.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program. The device will undergo packaging and sterilization procedures similar to devices currently marketed and distributed by Cook Urological, Incorporated and Cook Ob/Gyn. Being similar with respect to indications for use, materials, and physical construction to predicate devices, this device meets the requirements for section 510 (K) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 29 2006

Ms. Cindy Rumple
Regulatory Affairs Technical Writer
Cook® Urological, Inc.
1100 West Morgan Street
SPENCER IN 47460

Re: K060908
Trade/Device Name: Cook® Sonohysterography Biopsy Catheter
Regulation Number: 21 CFR §884.1060
Regulation Name: Endometrial aspirator
Regulatory Class: II
Product Code: HFF
Dated: March 31, 2006
Received: April 3, 2006

Dear Ms. Rumple:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~Not Yet Assigned~~ K060908

Device Name: Cook® Sonohysterography Biopsy Catheter

Indications for Use: The Cook® Sonohysterography Biopsy Catheter is used to access the uterine cavity for sonohysterography and to obtain endometrial biopsy, if indicated, utilizing the same device. The device is a single catheter designed to perform saline infusion sonohysterography then, if indicated, biopsy of the endometrium using the same device. The device will be supplied sterile and is intended for one time use.

Prescription Use __X__ OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(Please do not write below this line-FDA use only-continue on another page if needed)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060908

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